

PATENT COOPERATION TREATY

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From the
 INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing
 (day/month/year) 03.12.2004

Applicant's or agent's file reference
 P60516/001

IMPORTANT NOTIFICATION

International application No.
 PCT/GB 03/04086

International filing date (day/month/year)
 23.09.2003

Priority date (day/month/year)
 23.09.2002

Applicant
 GW PHARMA LIMITED et al.

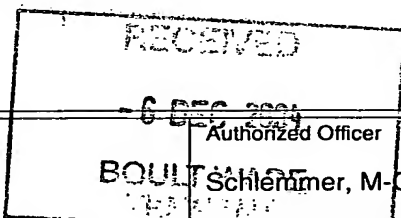
1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.



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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P60516/001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/04086	International filing date (day/month/year) 23.09.2003	Priority date (day/month/year) 23.09.2002
International Patent Classification (IPC) or both national classification and IPC C07C39/19		
Applicant GW PHARMA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 05.03.2004	Date of completion of this report 03.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Wörth, C Telephone No. +49 89 2399-8726 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB 03/04086

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-24 as originally filed

Claims, Numbers

1-24 filed with telefax on 17.11.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/04086**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-17
	No: Claims	18-24
Inventive step (IS)	Yes: Claims	1-17
	No: Claims	18-24
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/04086

1. Re Item I (Basis of the opinion)

1.1 Prior art

The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: DE-A-10106024

D2: Tetrahedron Letters, Elsevier Science Publishers, Amsterdam, NI (1985),
26(8), 1083-1086

D3: WO-A-03063847

D4: GB-A-2377633

D5: WO-A-02069993

D6: WO-A-0232420

D7: WO-A-02064109

In view of their publication date, documents D3 and D4 do not contribute to prior art within the meaning of Rule 64.1(b) PCT and will not be taken into consideration.

1.2 Amendments

With Telefax dated 17.11.2004, the Applicant submitted an amended set of claims 1-24 wherein

- originally filed claims 1, 2 and 8 were combined in new claim 1
- originally filed claims 6-8 were deleted
- originally filed claim 18 has been amended according to page 5, lines 16-20 (step vii in new claim 15)
- originally filed claim 21 has been amended (new claim 18)
- originally filed claim 26 has been amended (new claim 23).

The requirements of Art. 19 PCT are fulfilled.

2. Re Item V (Reasoned statement under Art. 35(2) PCT with regard to novelty,

inventive step or industrial applicability; citations and explanations supporting such statement)

2.1 Subject-matter

The present application discloses a method for obtaining cannabidiol (CBD) from plant material (independent claim 1) and a preparation of cannabidiol (independent claim 18).

2.2 Novelty

Independent claim 1 discloses a process of obtaining CBD characterized by

- obtaining a CBD-containing extract of plant material
- dissolving this extract in a solvent being a C₅-C₁₂ straight chain or branched alkane or a carbonate ester of a C₁-C₁ alcohol
- removing insoluble material from this solution
- evaporating the solvent.

Claim 1 differs from

D1 in view of the solvent specified in present claim 1

D2 in view of the isolation of cannabidiol from plant material

D5 in view of the absence of a chromatographic separation used in D5

D6 in view of the absence of a high pressure column extraction used in D6

D7 in view of the isolation of CBD (see examples 17 and 18 in D7).

The subject-matter of claims 1-17 fulfills the requirements of novelty.

Independent claim 18 discloses a preparation of CBD 'prepared from plant material' characterized by a chromatographic purity of 98% or greater.

Claim 18 is to be construed as a claim to the preparation as such and does not render the claimed preparation novel merely by the fact that it is prepared from plant material.

Furthermore, a document disclosing a low molecular chemical compound and its manufacture made this compound available to the public in all grades of purity as desired by a person skilled in the art, since it is common practice for a person skilled in the art of preparative organic chemistry to further purify a compound obtained by a particular process according to the prevailing needs and requirements.

In his letter of reply dated 27.08.204, the Applicant argues that the commercially available "Sigma Standard" has a purity of 93%, indicating to a skilled man that such standard is **purified to the highest degree of purity possible**. Accordingly, the Applicant concludes that an exceptional situation exists justifying the conclusion that the high degree of purity of CBD according to claim 18 establishes novelty.

The IPEA respectfully disagrees. The circumstances for recognising such a prejudice are very strict and has normally to be demonstrated by reference to the literature of to encyclopaedias and cannot be demonstrated by a reference to a commercially available standard, which itself has to be commercially attractive.

Accordingly, the disclosures of CBD in D2 (disclosing CBD as chromatographically pure oil and as crystalline material on page 1083, 3rd paragraph), D5 (see example 1), D6 (see tables 3 and 4) and D7 (see example 18) take away the novelty of claim 18.

The subject-matter of claims 18-24 do not fulfill the requirements of novelty.

2.3 Inventive step

Document D1 is at present considered as closest prior art. This document discloses in paragraphs [0008] and [0011] a process for obtaining CBD characterized by

- obtaining a CBD-containing extract of plant material
- dissolving this extract
- removing insoluble material from this solution
- evaporating the solvent.

In view of this document, the problem to be solved can be regarded as the provision of a further process for the preparation of CBD from plant material. The solution provided consists in a process according to claim 1.

The subject-matter of claim 1 is considered as involving an inventive step since none of the cited documents anticipates the use of a solvent being a C₅-C₁₂ straight chain or branched alkane or a carbonate ester of a C₁-C₁ alcohol in the work-up procedure of a cannabidiol plant extract. Furthermore, the high degree of purity obtained thereby is considered as an unexpected effect indicating an inventive step.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/04086

The requirements of Art. 33(3) PCT are fulfilled for the subject-matter of claims 1-17.

The subject-matter of claims 18-24 is related to a **preparation**. In order to fulfill the requirements of the EPC, this preparation has to be inventive *per se*.

The requirements to accord inventive step are:

- 1) The composition exhibits a **use** or an **effect** which is unexpected.
- 2) *Occasionally* when the composition has been produced by an inventive process. However, this is applicable **only** in the case where a **technical prejudice** to its production or **insurmountable difficulties** in its production were believed to exist. However, a composition is not automatically rendered inventive by an inventive process of its production.

Presently, none of the above identified criteria appear to be fulfilled.

The subject-matter of claims 18-24 does not fulfill the requirements of inventive step.